

REMARKS

In an Office Action mailed February 22, 2006, the Examiner withdrew the objection against claims 11-13, withdrew the indefiniteness rejection against claims 12 and 13, and withdrew the anticipation rejection against claims 2-4, 11, and 13 over Bonaldo et al. (Genome Research 6:791-806, 1996). However, the Examiner rejected claims 2-4, 11-13, and 16-18 under 35 U.S.C. § 112, first paragraph for failing to meet the written description requirement, rejected claims 2 and 11 under 35 U.S.C. § 112, first paragraph for encompassing new matter, rejected claims 2-4, 11-13, and 16-18 under 35 U.S.C. § 112, first paragraph for failing to meet the enablement requirement, and rejected claims 11-13 under 35 U.S.C. § 102(b) as being anticipated by Wu et al. (Biochim Biophys Acta 1315:169-175, 1996).

Applicants herein respond to each of the Examiner's rejections below. In view of the amendments noted above and the arguments presented herein, applicants respectfully request reconsideration of the merits of this application.

Written Description Rejection under 35 U.S.C. §112, First Paragraph

Claims 2-4, 11-13, and 16-18 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner alleged that the claims are drawn to a genus of nucleic acid molecules with various degrees of variations, i.e. 80-95% identity to the coding sequence of SEQ ID NO:1 and 3 and hybridizing molecules under the recited conditions to the coding sequence of SEQ ID NO:1 and 3, wherein the nucleic acid molecules in the genus encode a protein overexpressed in liver tumor cells relative to regenerating normal cells. In the Examiner's opinion, the written description is lacking for said genus of nucleic acid molecules.

Without agreeing with the Examiner, claims 2 and 11 are herein amended and claims 16-18 are canceled to facilitate prosecution. Applicants reserve the right to pursue the deleted subject matter in a subsequent application. Applicants respectfully submit that claims 2-4 and 11-13 as amended satisfy the written description requirement.

Claim 2 as amended is directed at an isolated nucleic acid comprising a coding sequence for a polypeptide selected from the group consisting of SEQ ID NO:2 and SEQ ID NO:4. For clarity purpose, the subject matter related to a coding sequence of SEQ ID NO:1 and a coding sequence of SEQ ID NO:3 is moved to a new claim, claim 19, which depends

on claim 2. As applicants disclosed SEQ ID NO:2 and 4 in the application, a skilled artisan can certainly envision the corresponding coding sequences by their structure (i.e., the nucleotide sequences) because the genetic code is well known in the art. For any given sequence, there will not be any confusion as to whether it is a coding sequence for SEQ ID NO:2 or 4. Further, SEQ ID NO:1 and 3 are also disclosed by the applicants. Accordingly, the written description requirement for claims 2-4 as amended and new claim 19 is satisfied.

Claim 11 has been amended to limit the oligonucleotide and polynucleotide to those that hybridize to a coding sequence of SEQ ID NO:1 and a coding sequence of SEQ ID NO:3 under much more stringent hybridization conditions. Support for the more stringent hybridization conditions can be found at paragraph [00030] on page 6 of the application. The specific coding sequences of SEQ ID NO:1 (nucleotides 35-859) and SEQ ID NO:3 (nucleotides 1-825) along with the newly recited, much more stringent hybridization conditions put a structural limitation (i.e., nucleotide sequence limitation) on the nucleic acid molecules that can hybridize. For example, from the lowest temperature at which only homologous hybridization occurs with a particular concentration of salt (e.g., SSC), 1% mismatching results in about 1°C decrease in the T_m. Therefore, with the specific washing salt concentration and temperature provided, a skilled artisan can readily determine with reasonable certainty whether any given nucleotide sequence can hybridize to nucleotides 35-859 of SEQ ID NO:1 or nucleotides 1-825 of SEQ ID NO:3. In addition, the application provides that the hybridizing oligonucleotides and polynucleotides at issue are useful as probes for detecting the expression of SEQ ID NO:1 and 3 (see e.g., paragraph [00019], lines 1-5 and paragraph [00028], lines 3-5). As a result, a skilled artisan would clearly recognize that applicants invented these nucleic acid molecules. For the above reasons, applicants respectfully submit that the written description requirement for claims 11-13 as amended is satisfied.

New Matter Rejection under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 2-4 and 11-13 alleging that the previously added limitation “80% identity to the coding sequence of SEQ ID NO:1 or 3” in base claims 2 and 11 is not supported by the specification.

Applicants first note that said limitation had been deleted from base claim 11 in connection with the last response. In addition, said limitation has also been deleted from base claim 2 in this response. The deletion of the limitation was intended for facilitating prosecution and does not represent that applicants agree with the Examiner. Applicants reserve the right to pursue the deleted subject matter in a subsequent application.

In view of the claim amendments, withdraw of the new matter rejection is respectfully requested.

Enablement Rejection under 35 U.S.C. §112, First Paragraph

Claims 2-4, 11-13, and 16-18 stand rejected under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. According to the Examiner, the specification is enabling for SEQ ID NO:1 and 3 and nucleic acids encoding SEQ ID NO:2 and 4 but not other nucleic acid molecules. Without agreeing with the Examiner, claims 2 and 11 are herein amended and claims 16-18 are canceled to facilitate prosecution. Applicants reserve the right to pursue the deleted subject matter in a subsequent application. Applicants respectfully submit that claims 2-4 and 11-13 as amended satisfy the enablement requirement.

Claim 2 as amended is directed at an isolated nucleic acid comprising a coding sequence for a polypeptide selected from the group consisting of SEQ ID NO:2 and SEQ ID NO:4. For clarity purpose, the subject matter related to a coding sequence of SEQ ID NO:1 and a coding sequence of SEQ ID NO:3 is moved to a new claim, claim 19, which depends on claim 2. As the Examiner indicated in the office action, the subject matter of claims 2-4 as amended and new claim 19 is enabled.

Claim 11 has been amended to limit the oligonucleotide and polynucleotide to those that hybridize to a coding sequence of SEQ ID NO:1 and a coding sequence of SEQ ID NO:3 under much more stringent hybridization conditions. The specification has clearly demonstrated that SEQ ID NO:1 and 3 are overexpressed in liver tumor cells relative to regenerating normal cells. Further, the specification provides that the oligonucleotides and polynucleotides at issue can be used to detect the expression of SEQ ID NO:1 or 3. It is well within the capability of a skilled artisan to make said oligonucleotides and polynucleotides

and to use them for detecting the expression of SEQ ID NO:1 and 3. Accordingly, applicants respectfully submit that claims 11-13 as amended are enabled.

Anticipation Rejections under 35 U.S.C. §102 (b)

The Examiner rejected claims 11-13 as being anticipated by Wu et al., alleging that the primer containing "CGGAC" disclosed by Wu et al. at page 170, left column would hybridize to the "gcctg" of nucleotides 115-119 of SEQ ID NO:1 under the recited conditions. Without agreeing with the Examiner, claim 11 is herein amended to facilitate prosecution and applicants reserve the right to pursue the deleted subject matter in a subsequent application.

Claim 11 is amended to recite much more stringent hybridization conditions. Applicants respectfully submit that the primer containing "CGGAC" disclosed by Wu et al. will no longer hybridize to the "gcctg" of SEQ ID NO:1 under the more stringent hybridization conditions.

Furthermore, applicants note that claim 11 is a kit claim that comprises the hybridizing nucleic acid molecules as well as positive and negative controls. Wu et al. did not disclose such a kit. The primer containing "CGGAC" disclosed by Wu et al. is an adapter for facilitating the subtractive hybridization but not part of a sequence that is overexpressed in liver tumors (see page 170, left column as well as Fig. 1 and related text). Therefore, a skilled artisan would not have included such a primer/adapter with positive and negative controls to form a kit useful for diagnostic purposes.

For the above reasons, applicants respectfully request the anticipation rejection be withdrawn.

Rejoinder

Previously withdrawn method claim 6 and withdrawn claim 7 as amended are limited by the nucleic acids recited in elected composition claim 2 and they are believed to be eligible for rejoinder in accordance with MPEP 821.04 if claim 2 is found allowable. Previously withdrawn method claim 9 as amended is also believed to be eligible for rejoinder as a dependent of claim 7. Applicants respectfully request that these claims be rejoined.

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Reply to Office Action dated: 02/22/2006



Summary

Claims 2-4, 6, 7, 9, and 11-13 as amended as well as new claim 19 are believed to be in condition for allowance and a Notice of Allowance is respectfully requested. Should any issue remain outstanding, the Examiner is invited to contact the undersigned at the telephone number appearing below if such would advance the prosecution of this application.

Respectfully submitted,

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